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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :
A61N 1/362, 1/372, 1/375
A61N 1/378

A1

(11) International Publication Number: WO 92/20402

(43) International Publication Date: 26 November 1992 (26.11.92)

(21) International Application Number: PCT/AU92/00219

(22) International Filing Date: 15 May 1992 (15.05.92)

(30) Priority data:
PK 6207 17 May 1991 (17.05.91) AU

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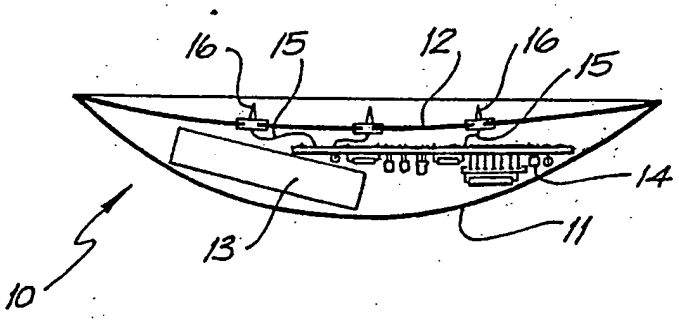
(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC (European patent), MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, RU, SD, SE, SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.

(54) Title: A PACEMAKER FOR A HEART



(57) Abstract

A pacemaker for a heart in the form of a container (10) which houses electronic circuitry which generates the necessary pulse to activate a patient's heart. The pacemaker is part hemispherical in shape and has an outer convex surface (11) and an inner concave surface (12). Electrode (16) protrudes through the concave surface (12) and the periphery of the container is connected to the outer surface of a heart whereby the electrodes contact mio-cardial cells.

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A PACEMAKER FOR A HEART

The present invention relates to a new cardiac pacemaker.

Existing cardiac pacemakers consist of a power source and electronic circuitry which together constitute a pulse generator housed within an hermetically sealed metal capsule. The metal capsule is arranged to be inserted within a patients body normally near one of the pectoral muscles. An insulated lead having its proximal end connected into a receiving port of the metal capsule so as to provide a direct connection with the pulse generator, has its distal end connected to one or more bare metal electrodes which are located inside the patients heart.

To stimulate the heart tissue the pacemaker produces pulses periodically at the electrode. Typically each pulse has a voltage amplitude above the stimulating threshold voltage required to cause capture and thereby consistent pacing of the heart.

A problem inherent in the above described pacemaker is that users have all noted that for a period of some three weeks after implantation of a pacemaker system that the stimulating threshold voltage required to cause capture and thereby consistent pacing of the heart, increased considerably, irrespective of the type of electrode used.

A typical increase would be from 0.5 volts to 3 volts. Accordingly during implantation procedures many cardiologists would set the pacemaker output voltage to 5 volts to give them a perceived safety margin of 2 volts above the threshold. At some subsequent consultation the cardiologist concerned may test the threshold again and readjust the stimulating voltage.

After implantation of the pacemaker in all cases it is noted that fibrous tissue grows around the stimulating electrodes and the metal (titanium) capsule of the pacemaker pulse generator over a period of time.

The conventional cardiac pacemaker as described

above, has a number of drawbacks. Firstly, the procedure for inserting the pacemaker and its accompanying lead, is quite complex and requires the use of an X-ray fluoroscope to enable the lead from the pacemaker to be threaded through a vein to the heart so that the lead with the electrodes is positioned so that the electrodes are entrapped within heart tissue. The expertise and equipment required for the implantation technique described above is generally prohibitive for many third world countries.

Because the lead interconnecting the electrodes and the pulse generator is quite long, the impedance of the lead is significant in the design of the pulse generator. In addition, the lead is subject to degradation over a period of time which also degrades the signal which is transmitted to the electrodes. Further, there are problems associated with the intrusion of the lead within a particular vein or artery and other problems such as, subdermal irritation and possible subdermal eruption can occur, particularly in thin people, due to movement of the metal capsule housing the pulse generator. Accidental skeletal muscle stimulation due to degradation of the lead can also occur. There is also the problem that the electrodes can become dislodged from the heart tissue.

The metal capsule which houses the pulse generator can also be quite large, for example, 47 x 51 x 6mm and have a weight of 30 grams, in addition, a large portion of the metal capsule is necessary in order to provide a point of connection for the lead to the pulse generator.

According to one aspect of the present invention there is provided a pacemaker for a heart comprising a container, a pulse generator, a power supply and at least one electrode, the or each electrode being arranged on a first surface of the container, and the container when in use, being arranged to be connected to a heart whereby the or each electrode contacts the heart.

Preferably, the electrode is securely connected to the container.

There may be two electrodes comprising a cathode and an anode.

The container may be a moulded plastics material.

Preferably, the or each electrode is integrally formed with the container.

The or each electrode may comprise an attachment means for attaching the or each electrode to the heart of a patient.

The pacemaker may comprise a connecting means, so that when in use, the container may be connected to the heart.

It is preferred that the connecting means comprise, either hooks, harnesses or straps.

The connecting means may be integrally formed as part of the container.

The container, preferably is made from polyurethane.

The or each electrode is connected to the container through a base pad on the first surface of the container. The base pad is preferably made of polyurethane.

When in use, the first surface may be arranged to be directly opposite the heart.

The or each electrode may have an insulating portion adjacent the container.

The or each electrode may be platinum alloy.

The or each electrode may be arranged to extend through the container.

The or each electrode may be inserted into the heart tissue.

The or each electrode may be shaped with it's distal end larger than it's proximal end. (eg like a mushroom with it's head inserted into the heart tissue to insure permanent contact with same)

A proximal end of the or each electrode may be

connected directly to the pulse generator.

The or each electrode may be integrally formed with the pulse generator.

It is preferred that the power supply be a battery located inside the container.

The battery may be connected through circuitry to the pulse generator.

The battery may be externally attachable and removable to the container from a remote location through electrical cables.

The battery is preferably rechargeable.

The container is preferably an hermetically sealed chamber containing the power supply pulse generator and proximal ends of the or each electrode.

The or each electrode may be connected through wiring inside the container, to the pulse generator.

The container desirably is part hemispherical in shape with the or each electrode being arranged on a concave surface of the part hemisphere.

Preferably, the concave surface is arranged to be connected to the heart.

The container may be connected to the heart by chemical bonding or surgical stitching.

Preferably, the electrical parameters of the pulse generator are adjustable between predetermined limits.

The pulse width generated by the pulse generator is preferably .5 milliseconds for .3 to 1 volt or .3 to 2 milliamps.

Preferably, for a pulse width of less than .3 milliseconds, the voltage is two to ten volts.

Preferably, the pulse width generated by the pulse generator is within .1 to 1.5 milliseconds in duration.

The surface of the container which surface is arranged to be connected to a heart, preferably has the shape of the surface of the heart to which it is to be connected.

According to another aspect of the present invention there is provided an attachment device for a pacemaker for a heart, comprising a body and a peripheral portion, the peripheral portion being arranged to be attached to a heart, the body portion being arranged to support the pacemaker.

The peripheral portion, preferably comprises a plurality of straps.

Preferably, there are four straps.

Each strap, preferably comprises a plurality of holes at a distal end, which holes are provided to permit the straps to be sewn to the heart tissue.

The attachment device body may be arcuate in shape.

The attachment device may be cup-shaped with the rim of the body comprising the peripheral portion.

The attachment device may comprise an outer convex surface and an opposing inner concave surface. The concave surface being the surface which is arranged to be attached to the surface of a heart.

The pacemaker may be fully contained within the attachment device.

Preferably, each strap comprises a hook for attaching that strip to the heart.

According to another embodiment of the present invention an electrode of the pacemaker may be provided on the peripheral portion or one or more of the straps of the peripheral portion.

Preferably, the attachment device comprises a resilient material.

Alternatively, the attachment device is in the form of a bag within which is located the pacemaker. The or each electrode of the pacemaker being arranged to protrude through the bag so that when the bag is connected to the surface of the heart.a heart, the or each electrode of the pacemaker contacts heart tissue.

According to another aspect of the present invention there is provided a pacemaker for a heart,

comprising at least one stimulating electrode, a pulse generator means for generating a series of pulses, the pulse generator means in use being arranged to deliver pulses of opposite polarity to the or each stimulating electrode.

Preferably the pulses are periodic.

The pulses may comprise an equal number of positive and negative pulses.

The pulses may also comprise a sequence of positive pulses followed by a sequence of negative pulses.

In a preferred embodiment of the present invention each pulse is followed by another pulse of opposite polarity.

Preferably each pulse of opposite polarity has a substantially identical wave form.

Each pulse may have a substantially identical wave form.

According to another embodiment the root mean squared (RMS) value of each waveform is identical.

The pulses preferably are current or voltage pulses.

Each pulse is preferably generated at successive equally spaced time intervals.

A sequence of pulses may be generated at successive equally spaced time intervals.

The pulse generator means preferably comprises a pulse generator.

The pulse generator means can comprise switching circuitry for switching pulses from positive to negative.

It is preferred that the pulse generator means comprises a timer circuit for determining the time interval separating each pulse.

The timer circuit may be connected with the pulse generator and the switching circuit.

Preferably the pulse generator means comprises a battery connected to the timer circuit and pulse generator.

According to an alternative form of the present invention the pulse generator is connected with an output

circuit of the pulse generator means.

The switching circuit may also be connected with the output circuit.

The pacemaker may be a self-contained unit which is arranged to be attached to a heart.

The timer circuit can be controlled to vary the time interval between successive pulses.

The pulse generator means can be controlled to vary the amplitude of each pulse generated.

The pacemaker comprises two stimulating electrodes one acting as an anode the other as a cathode.

It is preferred that the pacemaker comprises an additional electrode acting as an indifferent electrode.

The pulse generator means may also comprises a microprocessor for controlling the pulse generator.

It is preferred that the pacemaker comprises a sensing electrode for sensing the current or voltage at the electrode when the pacemaker is in use.

Preferably when in use the pacemaker substantially eliminates polarisation at the or each stimulating electrode.

Preferred embodiments of the present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1A shows a bottom view of the pacemaker according to a first aspect of the present invention;

Figure 1B shows a side view of the pacemaker shown in figure 1A;

Figure 1C shows a sectional view of the pacemaker shown in figure 1A and figure 1B; and

Figure 2 shows an alternative embodiment of the pacemaker according to the present invention.

Figure 3 shows a pulse generator means in accordance with the present invention; and

Figure 4 shows pulses generated by the pulse generator means of figure 3.

The pacemaker shown in figures 1A, 1B and 1C, is a self contained hermetically sealed unit which may be made

of a resilient plastics material or metal. The pacemaker is cup-shaped or part hemispherical and comprises a convex surface 11 which forms the outer part of the part hemisphere, and a concave surface 12 which opposes the convex surface 11. The two surfaces 11 and 12 form a container 10 which houses electronic circuitry which generates the necessary pulse to activate a patients heart.

As shown in figure 1C, the electronic componentry consists of a power supply 13, pulse generator circuitry 14 and wiring 15 which connects the pulse generator circuitry to electrodes 16.

It is also possible to make the pulse generator with electrodes integrally formed therewith, so that when the pulse generator is housed in container 10, the electrodes 16 protrude therethrough insulated from the concave surface 12 by base pads 17. This eliminates impedance due to wiring.

The electrodes 16 are arranged to extend outwardly from the concave surface 12 so that when the pacemaker 10 is connected to a patients heart, the electrodes 16 contact heart tissue and are preferably close, if not in contact with mio-cardial cells.

It is envisaged that the pacemaker be attached to the heart tissue by either chemical bonding, surgical stitching or by hooks or strapping which form part of the container 10 of the pacemaker.

Typically, the pacemaker is inserted by an operation which involves placing the pacemaker on a patients heart and physically attaching it to the outer surface of the heart. The patients heart will therefore, beat with the pacemaker attached to its outer surface. Previously, it was not considered possible to attach a pacemaker to a patients heart without interfering with the beating of the patients heart. It is envisaged that the size of the pacemaker be no larger than 30mm x 30mm x6mm and that its weight be below 15 grams.

In operation, the pulse generator powered by the

power supply 13 is arranged to produce a pulse of duration preferably, between .3 and 1.2 milliseconds. At a pulse duration of less than .3 milliseconds, the stimulation threshold (the lowest voltage or current amplitude necessary to consistently evoke cardiac excitation outside the refractory period of the heart) rises very sharply but with a pulse duration of greater than 1.2 milliseconds, the stimulation threshold does not alter appreciatively. It is preferred that the voltage be in the range of .3 to 10 volts and the current be in the range of .3 to 2 milliamps. A typical example is a .5 millisecond pulse having a voltage of 1 volt and a current of 1 milliamp. Because the electrodes 16 are virtually directly connected to the pulse generator circuitry 14, there is very little impedance to the signal generated by the pulse generator, thus, it is not necessary to generate higher voltages and currents for a longer duration in order to overcome impedance introduced by leads which are required with conventional pacemakers. The result is a smaller pacemaker can be produced because the power requirements of the pulse generator are also reduced.

In the example shown in figures 1A, 1B and 1C, three electrodes are shown, one being the anode, one being the cathode and one being the sensing electrode. Because the pacemaker can be surgically implanted on a patients heart, the electrodes do not have to be in close contact with each other, thus, allowing a pacemaker to be designed which maximises the potential difference between the anode and a cathode by having them spaced apart and which allows the option of a sensing electrode which can be isolated from the other electrodes so as to avoid the possibility of false readings during pacemaker operation. In addition, the electrodes may be of much more delicate construction so that they may be implanted/ inserted into cardiac muscle to allow muscle tissue of the heart to grow into the electrodes if desired and to allow great flexibility with the design of the shape of the

electrode.

Further, because the pacemaker is attached to the patients heart, all the electrodes are at the heart including the normally large "indifferent electrode", i.e., the anode electrode, when a unipolar electrode is utilised. The size of the electrodes can also be optimised to take account of their advantageous location, i.e., at the heart.

Typically, with a conventional pacemaker utilising a lead, if a unipolar electrode system is adopted, the anode is located at the pulse generator while the cathode is located at the heart, thus, the potential difference between the cathode and the anode is more intrusive on the other organs of the patients body and is susceptible to lower accuracy due to the distance between the anode and the cathode. With the present pacemaker as previously described, the anode and cathode may be effectively in the same locality anywhere on the surface of the pacemaker container 10, thus, isolating the potential difference to the heart alone. Also, because the cathode and anode may be located anywhere on the surface of the pacemaker container, the arrangement may be designed to minimise local fibrosis and ischaemia by providing more than one cathode and anode pair, which may be used alternately by switching circuitry within the pacemaker container 10. The distance between the anode and cathode can also be optimised to enable a lower powered pulse generator to be used. In addition, a further electrode may be introduced purely as a test electrode which senses the potential difference between the cathode and itself or the anode and itself to ensure correct operation of the pacemaker.

According to another aspect of the present invention as shown in figure 2, the pulse generator may be housed within a flexible cup-shaped or umbrella-shaped container 18 again having a convex surface 19 and concave surface 20 which form a thickened body portion 21 in which the pulse generator circuitry is located and four

symmetrically arranged straps 22 which extend upwardly from the apex of body portion 21. Each strap comprises part of the convex outer surface 19 and convex inner surface 20 and further comprises eyelets 23 which enable the pacemaker container 18 to be stitched to a patients heart and hooks 24 which may be used in conjunction with the stitching to provide added securing of the pacemaker container or used instead of the stitching.

The electrodes of the pacemaker may be located in one or more of the straps or may be located in the central region of the concave inner surface 20.

Preferably, the concave surface 20 closely approximates the curvature of the part of the heart to which it is to be attached.

Preferably, it is surgically implanted and attached to the cardiac muscle under the pericardium.

Preferably, the electrodes make direct contact with the cardiac muscle in the region of the ventricular apex, thereby inducing state of the art cardiac pacing. The provision of the straps enables the pacemaker container to be of a more consistent shape which can be attached to any shaped heart.

A more detailed diagram of the electronic circuitry required to make the pacemaker will be described with reference to figures 3 and 4.

As shown in Figure 3 the pulse generator means 31 comprises a battery 32 which has one terminal connected with a timer circuit 33 and the other terminal connected with a pulse generator 34. The timer circuit 33 is connected with the pulse generator 34 and is also connected with a switching circuit 35. Both the switching circuit 35 and pulse generator 34 have output terminals which are connected to input terminals of output circuit 36. Output terminal 37 of the output circuit are then connected with stimulating electrodes.

In operation the battery charges the pulse generator which produces pulses at a constant frequency depending on the setting of timer circuit 33. The pulses generated

by the pulse generator 34 are all of the same sign and are transmitted to output circuit 36. The timer circuit 33 which has one of its outputs connected to switching circuit 35 synchronises the switching circuit with the frequency of the pulses produced by the pulse generator. The switching circuit 35 then switches the pulses at the output circuit after a time interval indicated by T. The length of the time interval T can be adjusted by adjusting a variable resistor or capacitor in either the switching circuit or timer circuit.

The output circuit serves as an interface between the electrode and the other circuit components thus ensuring correct impedance matching characteristics and isolating the electrodes from internal faults of the pulse generator means.

As shown in figure 4 typically a positive pulse is followed by a negative pulse after the time interval T. Each pulse has an amplitude of E volts and is identical although inverted with respect to the other pulse. The root mean squared (RMS) value of each pulse is substantially identical.

The pulses shown in figure 4 are repeated indefinitely.

In alternative embodiments of the present invention a series of positive pulses may be followed by a series of negative pulses and each series of pulses is separated by the time interval T. In addition the pulses may be current pulses rather than voltage pulses.

As previously mentioned the prior art pacemakers suffer from the problem of polarisation and therefore require the pacemaker output voltage to be increased over a period of time. The present invention however overcomes this problem by reversing the polarity of the pulses thus substantially reducing growth of fibrous tissue around each stimulating electrode.

According to another embodiment of the present invention, the pacemaker is provided with an array of electrodes so that the actual electrodes being used over

a period of time may be changed to prevent fibrosis occurring around any particular electrode. Accordingly, if a pair of electrodes is used initially after a predetermined amount of time, use of this first pair of electrodes can be discontinued and another pair of electrodes can be then used. Thus, the electrodes which are being used can be continuously changed to prevent any deleterious effects occurring around any particular electrode as a result of continued use of that electrode.

It is also possible to switch between different electrodes after a predetermined number of pulses, so that all the electrodes within the array are used continuously.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A pacemaker for a heart comprising a container, a pulse generator, a power supply and at least one electrode, the or each electrode being arranged on a first surface of the container, and the container when in use, being arranged to be connected to a heart whereby the or each electrode contacts the heart.

2. A pacemaker according to claim 1 wherein two electrodes are provided, one being a cathode, the other an anode.

3. A pacemaker according to claim 1 or 2 wherein the container is a moulded plastics material and the or each electrode is securely connected to the container.

4. A pacemaker according to any one of the preceding claims wherein the or each electrode has an attachment means for attachment to the heart.

5. A pacemaker according to any one of the preceding claims comprising a connecting means for connecting the container to the heart.

6. A pacemaker according to any one of the preceding claims wherein the connecting means comprises hooks or straps.

7. A pacemaker according to claim 5 or 6 wherein the connecting means is integrally formed as part of the container.

8. A pacemaker according to any one of the preceding claims wherein the or each electrode extends through the container.

9. A pacemaker according to any one of the preceding claims wherein the or each electrode has its distal end provided with a catch which is arranged to retain the distal end of the electrode in heart tissue.

10. A pacemaker according to any one of the preceding claims wherein the power supply is arranged to be located outside the container and is removably attachable thereto from a remote location by electrical cabling.

11. A pacemaker according to any one of claims 1 to

9 wherein the container is a hermetically sealed chamber having the power supply and proximal ends of the or each electrode located therein.

12. A pacemaker according to any one of the preceding claims wherein the container is part hemispherical in shape with a concave surface thereof being provided with the or each electrode.

13. A pacemaker according to any one of the preceding claims wherein the pulse width generated by the pulse generator is .5 milliseconds or .3 to 1 volt or .3 to 2 milliamps.

14. A pacemaker according to any one of claims 1 to 12 wherein the pulse generator has a pulse width of less than .3 milliseconds for a voltage of between 2 to 10 volts.

15. A pacemaker according to any one of claims 1 to 12 wherein the pulse generator generates a pulse width between .1 to 1.5 milliseconds.

16. An attachment device for a pacemaker for a heart, comprising a body and a peripheral portion, the peripheral portion being arranged to be attached to a heart, the body portion being arranged to support the pacemaker.

17. An attachment device as claimed in claim 16 wherein the peripheral portion comprises a plurality of straps.

18. An attachment device according to claim 17 wherein each strap comprises a plurality of holes at a distal end thereof, which holes are provided to permit the straps to be sewn to the heart tissue.

19. An attachment device according to any one of claims 16 to 18 wherein the body is arcuate in shape.

20. An attachment device according to any one of claims 16 to 19 further comprising an outer convex surface and an opposing inner concave surface which is arranged to be attached to the outer surface of the heart.

21. An attachment device according to any one of the

preceding claims comprising a compartment for the pacemaker.

22. An attachment device according to claim 17 wherein each strap comprises a hook for attaching that strap to the outside surface of the heart.

23. An attachment device according to any one of the preceding claims wherein an electrode of the pacemaker is provided on the peripheral portion.

24. An attachment device according to claim 17 wherein an electrode of the pacemaker is provided on one or more of the straps.

25. An attachment device according to any one of claims 16 to 24 which comprises a resilient material.

26. An attachment device according to any one of claims 17 to 25 wherein the attachment device is in the form of a bag within which is located the pacemaker, the or each electrode of the pacemaker being arranged to protrude through the bag so that when the bag is connected to the surface of a heart, the or each electrode contacts heart tissue.

27. A method of stimulating heart tissue comprising the steps of providing a pacemaker having a container, a pulse generator, a power supply and at least one electrode such that the or each electrode is arranged on a first surface of the container and connecting the container to heart tissue whereby a signal generated by the pulse generator is transmitted via the electrode to mio-cardial cells.

28. A method according to claim 27 wherein the container is surgically stitched to the heart tissue.

29. A method according to claim 27 or 28 wherein the container comprises straps with hooks which are hooked into heart tissue prior to connection of each strap to heart tissue.

30. A pacemaker for a heart, comprising at least one electrode and a pulse generator means for generating a series of pulses, the pulse generator means in use being arranged to deliver pulses of opposite polarity to the or

each electrode.

31. The pacemaker as claimed in claim 30 wherein the pulses are periodic.

32. The pacemaker as claimed in claim 30 or 31 wherein the pulses comprise an equal number of positive and negative pulses.

34. A pacemaker according to any one of claims 30 to 33 wherein each pulse is followed by another pulse of opposite polarity.

35. A pacemaker according to any one of claims 30 to 34 wherein the root mean squared value of each wave form is identical.

36. A pacemaker as claimed in any one of claims 30 to 35 wherein a sequence of pulses is generated at successive equally spaced time intervals.

37. A pacemaker as claimed in any one of claims 30 to 36 wherein the pulse generator means comprises a pulse generator and switching circuitry for switching pulses from positive to negative.

38. A pacemaker according to claim 37 wherein the pulse generator means comprises a timer circuit for determining the time intervals separating each pulse.

39. A pacemaker according to claim 38 wherein the timer circuit is connected with the pulse generator and the switching circuit.

40. A pacemaker according to claim 39 wherein the pulse generator means comprises a battery connected to the timer circuit and pulse generator.

41. A pacemaker according to claim 40 wherein the pulse generator is connected with an output circuit of the pulse generator means and the switching circuit is also connected with the output circuit.

42. A pacemaker according to claim 41 wherein the timer circuit is controllable to vary the time interval between successive pulses produced by the pulse generator means.

43. A pacemaker according to claim 41 or 42 wherein the pulse generator means is controllable to vary the

amplitude of each pulse generated.

44. A pacemaker according to any one of claims 30 to 43 wherein the pacemaker comprises two stimulating electrodes, one acting as an anode, the other as a cathode.

45. The pacemaker according to claim 44 comprising an additional electrode acting as an indifferent electrode.

46. A pacemaker according to claim 45 further comprising a sensing electrode for sensing the current or voltage at the sensing electrode when the pacemaker is in use.

47. A pacemaker for a heart comprising a container, at least one stimulating electrode, a pulse generator means for generating a series of pulses, the pulse generator means in use being arranged to deliver pulses of opposite polarity to the or each stimulating electrode, the or each electrode being arranged on a first surface of the container and the container when in use, being arranged to be connected to a heart whereby the or each electrode contacts the heart.

48. A pacemaker for a heart as claimed in any one of claims 30 to 46 comprising a container which houses the pulse generator means and the or each electrode being arranged on a first surface of the container whereby in use, the container is arranged to be connected to a heart so that the or each electrode contacts the heart.

49. A pacemaker for a heart as claimed in any one of claims 1 to 15 comprising a pulse generator means for generating a series of pulses, the pulse generator means in use being arranged to deliver pulses of opposite polarity to the or each electrode.

50. A pacemaker as claimed in claim 49 comprising an array of electrodes which are each arranged to be used intermittently for stimulating heart tissue.

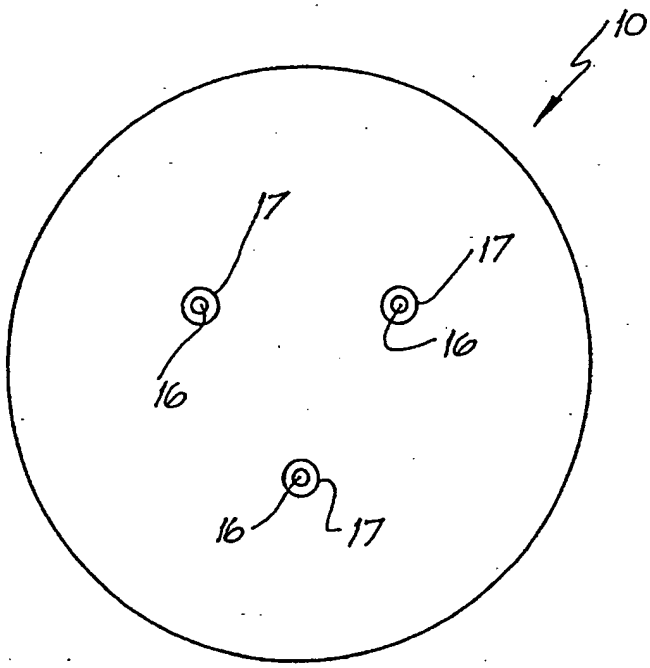


FIG. 1A

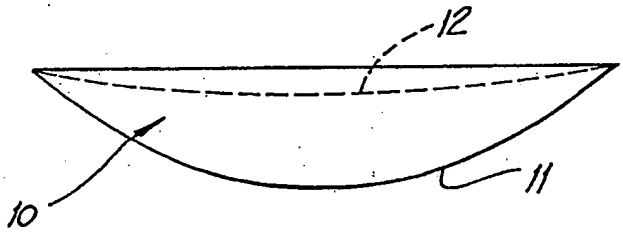


FIG. 1B

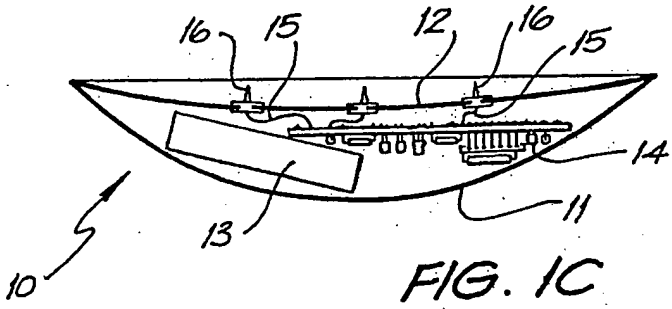


FIG. 1C

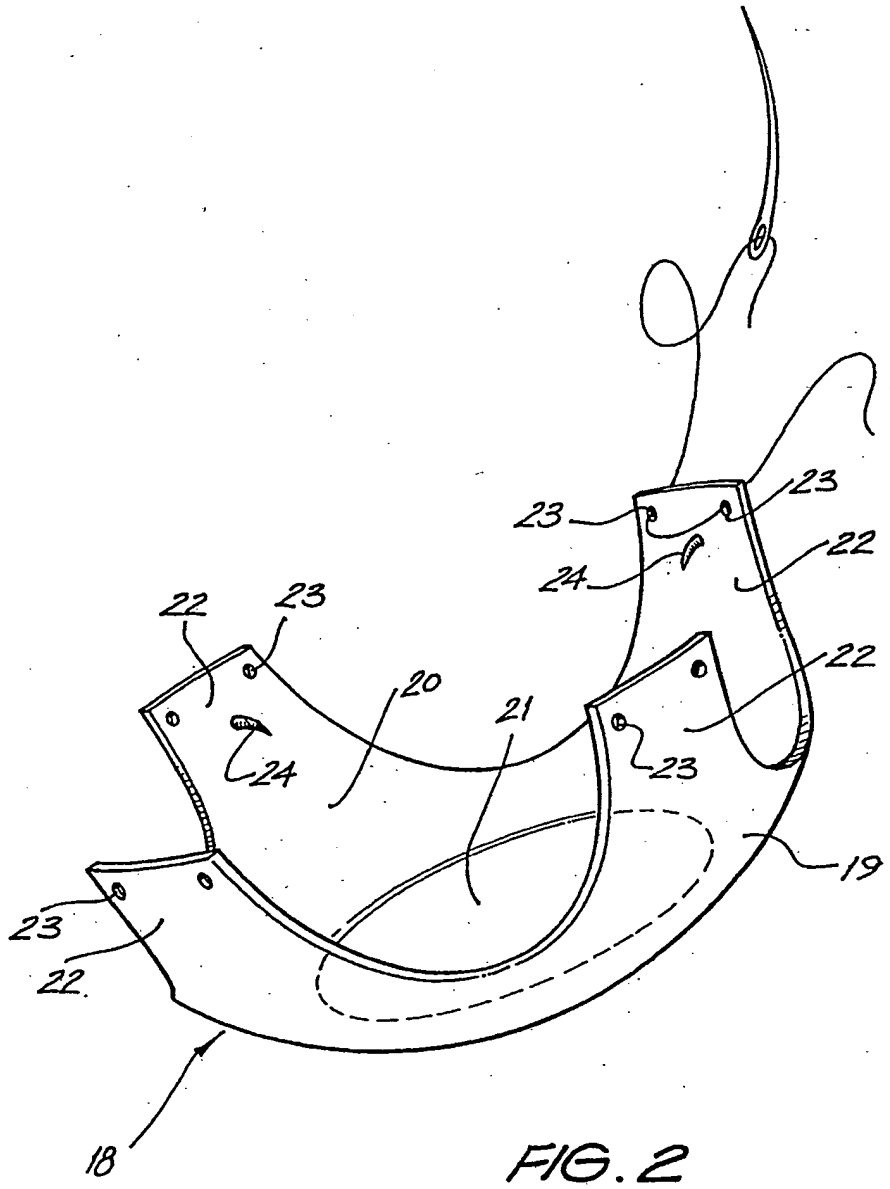


FIG. 2

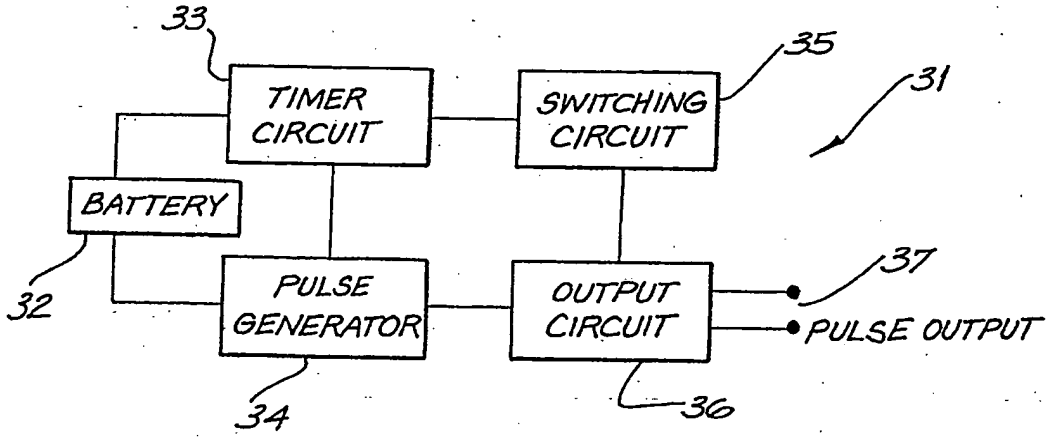
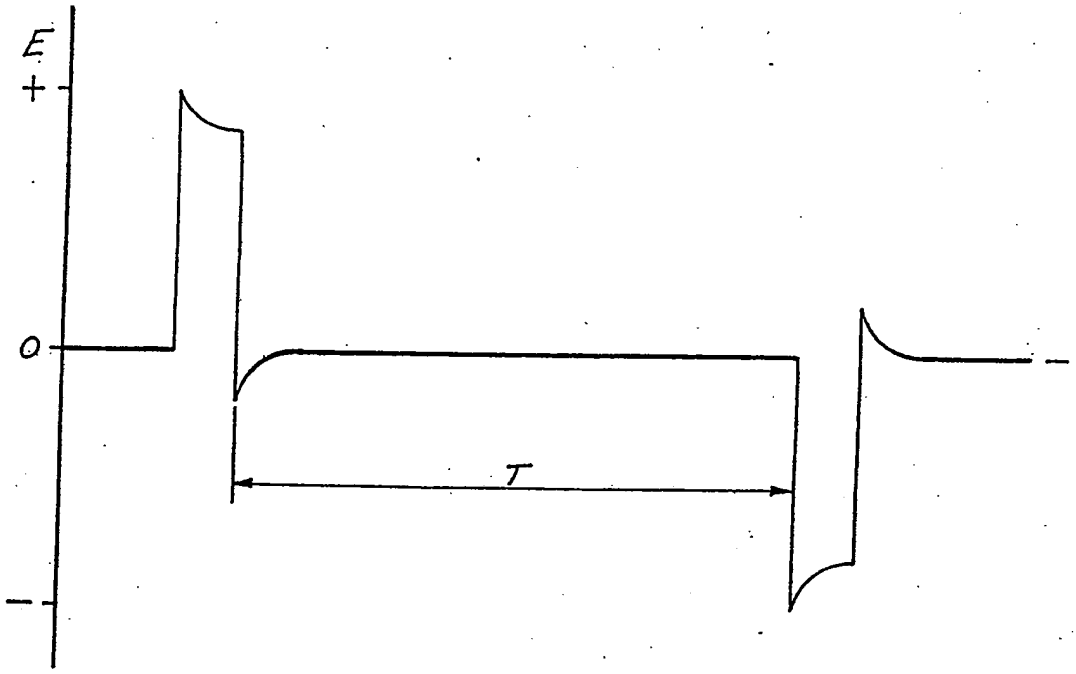

33
TIMER CIRCUIT
SWITCHING CIRCUIT
35
31
BATTERY
32
PULSE GENERATOR
OUTPUT CIRCUIT
37
PULSE OUTPUT
34
36

FIG. 3


E
+
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T

FIG. 4

INTERNATIONAL SEARCH REPORT

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent classification (IPC) or to both National Classification and IPC

Int. Cl.[5] A61N 1/362, 1/372, 1/375, 1/378

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC	A61N 1/36, 1/37, 1/362, 1/372, 1/375, 1/378

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category*	Citation of Document, [11] with indication, where appropriate of the relevant passages [12]	Relevant to Claim No [13]
A	WO,A, 88/03424 (S.B.M. SOCIETA BREVETTI PER LA MEDICINA) 19 May 1988 (19.05.88)	
A	WO,A, 91/08021 (MEDTRONIC INC) 13 June 1991 (13.06.91)	
A	US,A, 4770177 (SCHROEPPEL) 13 September 1988 (13.09.88)	
A	US,A, 4791931 (SLATE) 20 December 1988 (20.12.88)	
A, P	US,A, 5097833 (CAMPOS) 24 March 1992 (24.03.92)	

* Special categories of cited documents : [10]

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior t the international filing date but later than the priority date claimed

"T" Later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
31 July 1992 (31.07.92	11 Aug 1992 (11.08.92)
International Searching Authority	Signature of Authorized Officer
AUSTRALIAN PATENT OFFICE	R. TOLHURST

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim numbers ..., because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers ..., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out, specifically:

3. ☐ Claim numbers ..., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4a

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 30 - 46 are directed to a pacemaker which generates pulses of opposite polarity while the other claims are related to positioning a pacemaker adjacent the heart. There is no common novel feature between these two sets of claims.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL APPLICATION NO. PCT/AU 92/00219

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member
US 4791931	EP 307093 JP 1068279
WO 9108021	AU707372/91 US 5089019
WO 8803424	AU 82334/87 EP 294403 IT 8648643 IT 1214739